Registration Decision RD2012-26

Picoxystrobin

(publié aussi en français)

1 August 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2012-26E (print version)
H113-25/2012-26E-PDF (PDF version)

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Registration Decision for Picoxystrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Picoxystrobin Technical Fungicide and DuPont Acapela Fungicide, containing the technical grade active ingredient picoxystrobin, to control or suppress a broad spectrum of diseases on cereals, corn, dry legumes and soybeans.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-10, *Picoxystrobin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for picoxystrobin and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-10. This decision is consistent with the proposed registration decision stated in PRD2012-10.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-10, *Picoxystrobin* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Picoxystrobin?

Picoxystrobin is a fungicide active ingredient that controls or suppresses a broad spectrum of diseases in numerous crops. It has moderate uptake into host leaves through the xylem and exhibits translaminar movement.

Health Considerations

Can Approved Uses of Picoxystrobin Affect Human Health?

Picoxystrobin is unlikely to affect your health when used according to label directions.

Potential exposure to picoxystrobin may occur through the diet (food and water) or when handling and applying the product or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient picoxystrobin was of moderate acute toxicity by the inhalation route and was mildly irritating to the eyes; consequently, the hazard signal words "WARNING – POISON" and "EYE IRRITANT" are required on the label. It was of low acute toxicity orally and dermally. Picoxystrobin was non-irritating to the skin and did not cause an allergic skin reaction.

The acute toxicity of the end-use product DuPont Acapela Fungicide, containing picoxystrobin, was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes, slightly irritating to the skin and did not cause an allergic skin reaction. No hazard signal words are required on the label.

Health effects in animals given repeated doses of picoxystrobin included irritation of the mucous membranes throughout the gastrointestinal tract (G.I. tract). Picoxystrobin did not damage genetic material or cause cancer at doses that were relevant to human risk assessment. There was no indication that picoxystrobin caused damage to the immune system. Picoxystrobin did not cause birth defects in animals and there were no effects on reproduction. When picoxystrobin was given to pregnant or nursing animals, effects on the juvenile animal (decreased spleen weight) were observed at doses lower than those that were toxic to the mother, indicating that the young may be slightly more sensitive than the adult animal.

The risk assessment protects against the effects of picoxystrobin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children (1-2 yrs), the subpopulation which would ingest the most picoxystrobin relative to body weight, are expected to be exposed to less than 3% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from picoxystrobin is not of concern for all population sub-groups. There were no cancer risks of concern.

An aggregate (food and water) dietary intake estimate for the highest exposed population (all infants, <1 year old) used less than 1% (95th Percentile) of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using picoxystrobin on corn (field and sweet), wheat, barley, soybean, dried pea, dried bean and imported canola are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Proposed Registration Decision PRD2012-10, *Picoxystrobin.*

Occupational Risks From Handling DuPont Acapela Fungicide

Occupational risks are not of concern when DuPont Acapela Fungicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply DuPont Acapela Fungicide as well as field workers re-entering recently treated fields can come in direct contact with picoxystrobin residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying DuPont Acapela Fungicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing and loading and a long-sleeved shirt, long pants and shoes

plus socks during application. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, it was determined that the risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Picoxystrobin Is Introduced Into the Environment?

Picoxystrobin can pose a risk to earthworms, beneficial predatory and parasitic arthropods, non-target terrestrial plants and freshwater aquatic invertebrates, fish, amphibians and algae; therefore, statements on the product label are required to inform users of the potential risks, and spray buffer zones are required during application.

When picoxystrobin is applied as a fungicide in field crops, some of the active ingredient finds its way into soil and water. Picoxystrobin has low solubility in water and will partition to sediments. Picoxystrobin is broken down by microbial activity in soil, sediment and water; thus, it is not expected to persist in the environment. Four major transformation products (Compounds 2, 3, 7 and 8) may be present in soil or aquatic systems for a longer period of time. Compound 26 is a volatile transformation product formed in soil. Laboratory and field studies indicate that picoxystrobin and its transformation products have low mobility in soil and have low potential to leach to groundwater, except for one transformation product at one field site where precipitation levels were very high. Picoxystrobin and its transformation products are not expected to carry over in important amounts into the next growing season. Picoxystrobin does not appreciably bioconcentrate in fish. Picoxystrobin is not volatile and therefore not expected to be subject to long-range transport in the atmosphere. There is some uncertainty as to the persistence and potential for long-range transport of Compound 26, a major volatile transformation product formed in soil.

Picoxystrobin can be applied by field sprayer or aerial application. There is a potential that non-target terrestrial and aquatic habitats may be exposed to the chemical as a result of spray drift or runoff. Picoxystrobin is not expected to pose a risk to bees, birds, small mammals, freshwater vascular plants and marine/estuarine organisms at the proposed use rates. Picoxystrobin exposure can present a risk to earthworms, beneficial predatory and parasitic arthropods, terrestrial plants, and freshwater invertebrates, fish, amphibians and algae; therefore, statements on the product label are required to inform users of the potential risks. In order to minimize the potential for exposure resulting from off-field drift, no-spray buffer zones will be required between the treated area and downwind aquatic habitats. No environmental risk was identified from exposure to the major transformation products of picoxystrobin.

Value Considerations

DuPont Acapela Fungicide is a broad-spectrum fungicide with locally systemic activity for control of foliar plant diseases.

DuPont Acapela Fungicide controls or suppresses primary diseases of major field crops grown in Canada and can be integrated into a spray program as a rotational product or tank mix partner.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of DuPont Acapela Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with picoxystrobin residues on the skin or through inhalation of spray mists, anyone mixing, loading and applying DuPont Acapela Fungicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing and loading and a long-sleeved shirt, long pants and shoes plus socks during application. In addition, standard label statements to protect against drift during application are on the label.

The label must also include the following restrictions:

1. If wheat forage will be harvested, make only one application.
2. If soybean forage and hay will be harvested, make only one application.
3. All other crops not on the label may be planted after 10 months following the last application of picoxystrobin.

Environment

Picoxystrobin can pose a risk to earthworms and beneficial predatory and parasitic arthropods when used in Integrated Pest Management strategies. Label statements informing the users of the potential risks to these organisms are specified on the product label.

Spray drift of picoxystrobin can pose a risk to non-target terrestrial vascular plants, freshwater aquatic invertebrates, fish, amphibians and algae. To mitigate potential exposures via spray drift, spray buffer zones of 1 to 2 metres are required to protect sensitive terrestrial habitats, and spray buffer zones of 1 to 35 metres, depending on the type of application equipment and the crop, are required to protect sensitive aquatic habitats. These spray buffer zones are specified on the product label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-10, *Picoxystrobin)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*